REMARKS

A. BACKGROUND

The present Amendment is in response to the Office Action mailed September 2, 2009. Claims 1-14, 16, and 18-35 were pending, claims 1-13, and 18 were previously withdrawn, and claims 14, 16, and 19-35 were rejected in view of cited art. By this amendment, claim 35 is canceled, claims 14, 19, and 30-34 are amended, and no new claims are added. Claims 1-14, 16, and 18-34 are now pending in view of the above amendments.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, are consistent with the Examiner's understanding.

B. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The Office Action rejected claims 14, 16, and 19-35 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Claim 35 has been canceled herein; with respect to the remaining claims, Applicant respectfully traverses.

The Office Action alleges that the language reciting "a perfusion catheter configured for local administration of the restenosis inhibiting moiety to the intravascular medical device at an implantation site in the patient vessel after implantation of the intravascular medical device" "changed the scope of the invention by more broadly claiming a device not contemplated previously" and that this perfusion catheter "was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the

application was filed, had possession of the claimed invention." (Office Action, pg. 3) Applicant respectfully disagrees.

A perfusion catheter configured for local administration of a radioactive moiety and/or a neutron-capture moiety to an intravascular medical device after implantation at an implantation site in the patient vessel, as claimed herein, is recited and described in many parts of the pending application. For instance, the Abstract states that "after implantation of a stent, radioactive moieties specific for receptors immobilized on the stent surface are locally administered using a balloon perfusion catheter." In addition, the as-filed Application presents detailed illustrations and discussion of perfusion catheters that can be used to deliver a radioactive moiety and/or a neutron-capture moiety to an intravascular medical device after implantation of the medical device at a treatment site. (See, e.g., Figures 4, 5A, and 5B and paragraphs [0269]-[0305][1]) Reconsideration of claims 14, 16, and 19-34 is respectfully requested.

C. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The Office Action rejects claims 14, 16 and 19-35 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claim 35 has been canceled herein; with respect to the remaining claims, Applicant respectfully submits that the amendments presented herein are sufficient to overcome the rejections.

With particular reference to the recited "restenosis inhibiting moiety," the Office Action alleges that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

In response, claim 14 is amended herein to delete "restenosis inhibiting moiety," and claim 14 now recites, in part, "a radioactive moiety and/or a neutron-capture moiety . . . for inhibition of restenosis." Applicant respectfully submits that various radioactive moieties and/or neutron-capture moieties that can be used with the claimed kit are sufficiently described in the as-filed Application. In addition, specific examples of radioactive moieties and neutron-capture moieties were presented in as-filed claims 16 and 18. Reconsideration of claims 14, 16, and 19-34 is respectfully requested.

[1] Paragraph numbers used herein refer to the paragraph numbers used in the as-published Application. U.S. Pat. Pub. No. 2006/0078493.

D. PRIOR ART REJECTIONS

I. REJECTION UNDER 35 U.S.C. § 103

The Office Action rejected claims 14, 16, 19-23, and 28-35 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,871,436 (*Eury*) in view of U.S. Patent No. 5,871,437 (*Alt*) and in further view of U.S. Patent No. 5,873,811 (*Wang*). Claim 35 has been canceled herein; with respect to the remaining claims, Applicant respectfully submits that the amendments and remarks presented herein are sufficient to overcome the rejections. In particular, Applicant respectfully requests withdrawal of this rejection and allowance of the claims because the cited references, either alone or in combination, fail to teach or suggest each and every limitation of the claims, the claimed invention provides advantages that are neither taught nor suggested in the cited references, and there is no motivation to modify the references in order to yield the claimed invention.

In accordance with Applicant's understanding, *Eury* discloses an intravascular device (e.g., a stent) that is "coated with a chelator selected for its bonding affinity with a specific radio isotope." (Abstract). "Just **prior** to implantation, the [stent] is immersed in a solution of the radioisotope which enables a prescribed amount of such radioisotope to be adsorbed." *Id.* (emphasis added). Likewise, *Alt* discloses a stent that is coated with a radioisotope **prior** to implantation. (See, e.g., Abstract). In accordance with Applicant's understanding, *Wang* discloses coating a treatment area in a vessel with a radioactive adhesive or polymeric material to prevent restenosis. (Abstract). Application of the radioactive adhesive can be followed by stent placement. *Id.*

In contrast to the art of record, claim 14 is amended herein to recite, in part, "[a] kit for inhibiting restenosis in a patient vessel." The kit includes "an intravascular medical device" and "a perfusion catheter configured for local administration of a radioactive moiety and/or a neutron-capture moiety to the intravascular medical device **after** implantation at an implantation site in the patient vessel" (emphasis added). The "intravascular device" includes "a first member of a specific binding pair immobilized to the surface in a selected density and/or pattern" and the radioactive moieties and/or neutron capture moieties are each "bound to a second member of the specific binding pair, with the second member of the specific binding pair being capable of binding to the first member that is immobilized to the surface of the intravascular medical device in the selected density and/or pattern for delivery of a selected dose of radiation to the

implantation site in the patient vessel in a range from about 10^{-3} grays to about 1000 grays for inhibition of restenosis."

Applicant respectfully submits that no combination of *Eury*, *Alt*, or *Wang* teaches or suggests a kit that includes "an intravascular medical device" and "a perfusion catheter configured for local administration of a radioactive moiety and/or a neutron-capture moiety to the intravascular medical device **after** implantation at an implantation site in the patient vessel." In contrast, as mentioned above, the cited references either teach making a stent radioactive **prior** to implantation or teach applying a radioactive material to a vessel **prior** to implanting a stent. Applicant respectfully submits that a combination of *Eury*, *Alt*, and *Wang* can yield no more than a stent that is made radioactive prior to implantation, where the stent is implanted in a vessel that has a radioactive adhesive applied to the vessel wall. This falls well short of what is claimed herein.

Moreover, Applicant respectfully submits that the "kit" claimed herein may provide advantages that are neither taught nor suggested in the art of record. For instance, the presently claimed invention allows a practitioner to select at what time after implantation the intravascular device will be made radioactive, how much radioactivity will be applied to the intravascular device, the pattern and density of the radioactivity on the device, and the ability to apply radioactivity only to the device and not to the patient's circulatory system at large. In contrast, in the methods of *Eury* and *Alt*, making a stent radioactive and then traversing the patient's vasculature would necessarily result in the shedding of radioactive material throughout the anatomy traversed. This may be undesirable and may result in dosage outside the "implantation site." Likewise, Applicant has been unable to find any portion of *Wang* that indicates that its methods yield themselves to delivery of a "selected dose of radiation to the implantation site" and the density and/or pattern of radiation dosing being selected as in the presently claimed kit. Applicant respectfully submits that this may be the case at least insofar as the treatment site in the vessel provides an inconsistent surface for adhering the radioactive material, which leads to unpredictability in terms of the amount of radioactive material that adheres and reduces the ability to control the pattern or density of radioactivity. The over- or under-dosing or the inadvertent systemic dosing that may occur in the methods of *Eury*, *Alt*, and *Wang* may produce detrimental patient outcomes. The present invention overcomes these disadvantages and presents advantages that are neither taught nor suggested in the cited art.

In addition to the above, Applicant respectfully submits that there is no motivation to modify the cited references in order to yield the claimed invention. This is the case at least in part because the cited references fail to teach or suggest each and every limitation of the claims and the claimed combination provides advantages that are neither taught nor suggested in the cited art. Applicant respectfully submits that absent such motivation to modify, a rejection based on a combination of references is unsupported and any rejection based on such a combination must be withdrawn.

Based on the foregoing, Applicant respectfully submits that the Office Action has failed to present a *prima facie* case of obviousness and request that the rejection of claim 14 and the claims that depend thereon withdrawn. As such, Applicant respectfully requests reconsideration and allowance of claims 14, 16, 19-23, and 28-34.

E. CONCLUSION

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 2nd day of February, 2010.

Respectfully submitted,

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